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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,531	03/23/2004	David Feygin	115-003US	4765
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EXAMINER				
HU, KANG				
ART UNIT		PAPER NUMBER		
3714				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/806,531

**Applicant(s)**

FEYGIN ET AL.

**Examiner**

KANG HU

**Art Unit**

3714

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8, 10 and 12-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10 and 12-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 12/4/2007.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 26, 2007 has been entered. Claims 7, 9 and 11 have been cancelled. Claims 1-6, 8, 10, 12-28 are currently pending in the application.

### ***Specification***

2. The disclosure is objected to because of the following informalities: the first paragraph of the disclosure, "statement of related cases" was not filed out completely.

Paragraph 52 of the disclosure was not filled out completely.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Re claim 1 recites "angle of rotation" and "said needle and said catheter about a roll axis...;" the examiner failed to find in the specification of the application of any definitions of angle of rotation and long (i.e., roll) axis as explained on page 8 in the response from the applicant dated November 26th, 2007.

Appropriate action is required.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4-6, 8, 10, 12-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302 B1) in view of Rosenberg et al. (US 5,821,920).

Re claim 1, the teachings of Cunningham have previously been discussed in the office action June 29, 2007. Cunningham does not teach where the sensor senses an angle of rotation of at least one of: said needle and said catheter about a roll axis that is aligned with a length of needle, however Cunningham discloses in the specification knowing Rosenberg teaches of a pen-like stylus allows for dexterous 3-dimensional manipulation, and the position and orientation of the stylus is communicated to a host computer. The Immersion PROBE has six degrees of freedom which convey spatial coordinates (x, y, z) and orientation (roll, pitch, yaw) of the stylus to the

host computer. It would have been prima facie obvious to combine the teachings of Rosenberg, as Rosenberg also teaches creating a realistic simulation environment of laparoscopic surgery and catheter insertion and has been discussed by Cunningham in the specification. Cunningham further teaches the added limitation of pseudo skin (mock skin), wherein said pseudo skin comprises an opening for receiving said needle and catheter. Cunningham discloses that mock skin is well known in the art by disclosing "model includes a mock bodily region of interest" (col 1, 59-60); "internal arterial modeling device" and "mock arterial paths" (col 2, 4-5).

Cunningham further discloses the use of "skin traction mechanism" and "the computer system performs a simulation of the surface and subsurface anatomy of human skin" is also analogous to the use of mock skin (col 7, 5-7). Lastly Cunningham claims the use of mock skin in the claim language of claims 2 and 3. Rosenberg describes the use of skin for the same purpose (col 4, 62-68).

Re claim 4, a receiver for receiving at least one of said needle and said catheter is disclosed by Cunningham as a catheter unit assembly for receiving a catheter needle assembly (abstract). Cunningham does not explicitly disclose that the said receiver is disposed underneath said pseudo skin and covered by said pseudo skin, however it would have been inherent as the Cunningham's invented device is also used for simulating a catheter needle insertion, and it would simulate inserting the catheter/needle assembly underneath the skin as suggested by Cunningham (col 7, 1-20).

Re claim 5, said sensor is physically coupled to said needle (col 8, 30-37).

Re claim 6, a data processing system that receives a signal that is indicative of said angle of rotation (Rosenberg, col 6, 55-68; col 15, 1-13)

Re claims 12 and 20, Cunningham introduces pseudo skin, force-feedback assembly and end effector passing through the pseudo skin to couple with the force-feedback assembly. Cunningham explicitly discloses the use of pseudo skin in multi-areas of the specification and claims as explained in claim 1 above, Cunningham further introduces the use of force-feedback assembly in cols 7 and 8, even though Cunningham does not explicitly teach that the end effector passes through said pseudo skin and that the end effector are reversibly coupled to said force-feedback assembly, it would have been obvious as if the surface was covered by pseudo skin, one would have to insert the needle/catheter assembly or similar simulating devices through the pseudo skin. It would also be obvious to be able to attach and remove the end effector from the force-feedback assembly to simulate different devices and methods of performing different procedures. It would take only simple modifications to one of ordinary skill in accomplishing such task.

Re claims 8, 10, 13-19, 21-38 have been previously discussed in the office action Jun 29<sup>th</sup>, 2007 and will not be repeated herein.

7. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302 B1) in view of Rosenberg et al. (US 5,821,920) further in view of Grayzel (US 4,850,960) as indicated in the previous office action.

Re claims 2 and 3, Cunningham does not disclose that the catheter or the needle comprises a bevel. Grayzel teaches the feature of a catheter with a bevel tip helps to facilitate insertion of the catheter into a pre-existing puncture aperture, the bevel also serves to ease the introduction of the catheter through muscle walls among other advantages (col 4, 6-35). It would have been obvious to use a needle and catheter with bevel to simulate a more realistic experience in performing the needle/catheter insertion.

#### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1-6, 8, 10, 12-28 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KANG HU whose telephone number is (571)270-1344. The examiner can normally be reached on 8-5 (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3714

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kang Hu/  
Examiner, Art Unit 3714

/Ronald Laneau/  
Supervisory Patent Examiner, Art Unit 3714  
02/19/08